Summary of Safety and Effectiveness

Submitter:

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Date Prepared:

December 21, 2000

General Provisions

Trade Name: Cordis TrapEase™ Permanent Vena Cava Filter and Introduction Kit

Common Name: Permanent Vena Cava Filter and Introduction Kit

Classification Name: Cardiovascular Intravascular Filter (per 21 CFR 870.3375)

Device Classification: Class II

Name of Predicate Devices

The modified Cordis TrapEase™ Permanent Vena Cava Filter and Introduction Kit is substantially equivalent to:

- Cordis TrapEase™ Permanent Vena Cava Filter and Introduction Kit (510(k) #K000062)
- Simon Nitinol Filter/Straight Line™ System (510(k) #K963014)

Performance Standards and Special Controls

As per 21 CFR 870.3375, the following special controls were established for cardiovascular intravascular filters: (1) "Use of International Standards Organization's ISO 10993 'Biological Evaluation of Medical Devices Part I: Evaluation and Testing,' and (2) FDA's: (i.) "510(k) Sterility Review Guidance and Revision of 2/12/90 (K90-1)" and (ii) "Guidance for Cardiovascular Intravascular Filter 510(k) Submissions."

Device Description

The subject device is a system that consists of a flexible, symmetrical, self-expanding vena cava filter to be deployed in the infrarenal inferior vena cava via a 6F sheathed introduction kit. The filter is designed to trap large, life-threatening emboli and therefore prevent recurrent pulmonary embolism, while maintaining caval patency. The modifications to the subject device, namely the revision of device labeling to include antecubital delivery of the filter and to remove the recommendation to inject 5,000 IU of heparin at the beginning of the procedure, and the increase in the length of the device's sheath introducer, vessel dilator, guidewire and obturator to allow antecubital delivery of the filter, do not affect the intended use or basic fundamental technology of the device.

Intended Use

The intended use of the Cordis TrapEase Permanent Vena Cava Filter and Introduction Kit is prevention of recurrent pulmonary embolism via percutaneous placement in the inferior vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated,
- Failure of anticoagulant therapy in throboembolic diseases,
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced and chronic,
- and recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

This is the same intended use featured with the predicate device, the Cordis TrapEase Permanent Vena Cava Filter and Introduction Kit, (510(k) #K000062).

Performance Data:

The safety and effectiveness of the modified Cordis TrapEase™ Permanent Vena Cava Filter and Introduction Kit have been demonstrated via data collected from non-clinical design verification tests and analyses. The design verification testing consisted of the following:

- Simulated Deployment
- Catheter Sheath Introducer Suitability
- Visual and Dimensional inspection

Summary of Substantial Equivalence

The design, material, components, fundamental technology and intended use featured with the Cordis TrapEase Permanent Vena Cava Filter and Introduction Kit are substantially equivalent to those featured with the predecessor Cordis TrapEase Permanent Vena Cava Filter and Introduction Kit (reference 510(k) #K000062). The expanded method of delivery featured with the Cordis TrapEase Permanent Vena Cava Filter and Introduction Kit is substantially equivalent to that featured with the Simon Nitinol Filter/Straight Line™ System (Nitinol Medical Technologies, Inc.; reference 510(k) #K963014).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 9 2001

Cordis Corporation
a Johnson & Johnson Company
c/o Ms. Karen Wilk, RAC
Manager, Regulatory Affairs
7 Powderhorn Drive
Warren, NJ 07059

Re: K003964
Trade Name: Cordis TrapEase™ Permanent Vena Cava Filter and Introduction Kit
Regulatory Class: II (two)
Product Code: DTK
Dated: December 21, 2000
Received: December 22, 2000

Dear Ms. Wilk:

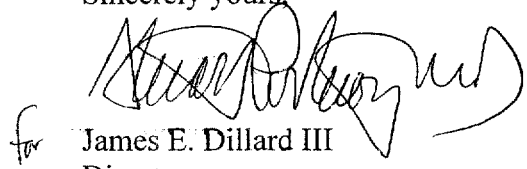
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4868. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Special 510 (k) Number: K003964

Device Name: **Cordis TrapEase™ Permanent Vena Cava Filter and Introduction Kit**

Indications For Use:

The Cordis TrapEase™ Permanent Vena Cava Filter is indicated for the prevention of recurrent pulmonary embolism via percutaneous placement in the inferior vena cava in the following situations: pulmonary thromboembolism when anticoagulants are contraindicated, failure of anticoagulant therapy in throboembolic diseases, emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced and chronic, and recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number _____

1-18-1

Division of Cardiovascular & Respiratory Devices
510(k) Number K003964